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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 5

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Application Number	09/966893
Filing Date	September 28, 2001
First Named Inventor	d'Azzo
Art Unit	1646
Examiner Name	To be assigned
Attorney Docket Number	SJ-01-0020

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US PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication or issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Name of Inventor(s)
CGJ	AA1	US-5,179,023	01-12-1993	Research Corp. Tech. Inc.	Calhoun et al.
	AB1	US-5,658,567	09-19-1997	Research Corp. Tech. Inc.	Calhoun et. al.
	AC1	US-5,762,939	06-09-1998	MG-PMC, LLC	Smith et. al.
	AD1	US-6,183,987	02-06-2001	Stichting Institut voor Dierhouderij en Diergegenhe	van de Weil et. al.
	AE1	US-6,225,060	05-01-2001	Onyx Pharmaceuticals, Inc	Clark et. al.
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	AI	US-			
	AJ	US-			
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Christina L. Fronde

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T ²
CJF	AR1	AEED, P.A. et al, "Glycosylation of recombinant prorenin in insect cells: the insect cell line Sf9 does not express the mannose 6-phosphate recognition signal", <i>Biochemistry</i> 33(29):8793-97 (1994)	
	AS1	AOKI, M. et al, "Improvement of neurological symptoms by enzyme replacement therapy for Gaucher Disease Type IIIb", <i>Eur. J. Pediatr.</i> , 160(1): 63-64 (2001)	
	AT1	BERG, T. et al, "Purification and characterization of recombinant human lysosomal alpha-mannosidase", <i>Mol Genet Metab.</i> , 73(1):18-29 (2001)	
	AU1	BIJSTERBOSCH, M.K. et al, "Quantitative analysis of the targeting of mannose-terminal glucocerebrosida; Predominant uptake by liver endothelial cells", <i>Eur. J. Biochem</i> , 237:344-349 (1996)	
	AV1	BONTEN, E J et al, "Lysosomal Protective Protein/Cathepsin A" <i>Journal of Biological Chemistry</i> 270(44): 26441-26445 (1995)	
	AW1	BONTEN, E J et al, "Catalytic Activation in Insect Cells is Controlled by the Protective Protein/Cathepsin A", <i>Journal of Biological Chemistry</i> 275(48): 37657-37663 (2000)	
	AX1	BONTEN, E J et al, "Correction of lysosomal PPCA and neuraminidase in mouse deficient macrophages after uptake of recombinant baculovirus-expressed proteins", <i>Amer. J. Hum. Gen. Suppl.</i> 69(4):Abst 1759 (2001)	
	AY1	BOOSE, J.A. et al, "Synthesis of a human lysosomal enzyme, beta-hexosaminidase B, using the baculovirus expression system", <i>Protein Expr. Purif.</i> 1(2):111-20 (1990)	
	AZ1	BROMME, D. et al, "High level expression and crystallization of recombinant human cathepsin S", <i>Protein Sci.</i> , 5(4):789-91 (1996)	
	AR2	CALHOUN, D.H. et al, "Fabry disease: Isolation of a cDNA clone encoding human α -galactosidase A", <i>PNAS</i> 82:7364-68 (1985)	
	AS2	CHEN, Y. et al, "Purification and Characterization of Human α -Galactosidase A Expressed in Insect Cells Using a Baculovirus Vector", <i>Protein Expression and Purification</i> 20:228-236 (2000)	
	AT2	COPPOLA, G. et al, "Characterization of glycosylated and catalytically active recombinant human alpha-Galactosidase A using a baculovirus vector", <i>Gene</i> 144(2):197-203 (1994)	
	AU2	D'AZZO, A., "Biochemical properties of PPCA and neuraminidase", Presentation at Strategies for Therapy of MPS and Related Diseases and 16 th Annual MPS Conference held on June 22, 2001 at UCLA	
	AV2	DAVIDSON, D.J. et al, "Oligosaccharide Processing in the Expression of Human Plasminogen cDNA by Lepidopteran Insect (<i>Spodoptera frugiperda</i>) Cells", <i>Biochemistry</i> 29(23): 5584-5590 (1990)	
	AW2	DAVIDSON, D.J. et al, "Asparagine-Linked Oligosaccharide Processing in Lepidopteran Insect Cells. Temporal Dependence of the Nature of the Oligosaccharides Assembled on Asparagine-289 of Recombinant Human Plasminogen Produced in Baculovirus Vector Infected <i>Spodoptera frugiperda</i> (IPBL-SF-21AE) Cells", <i>Biochemistry</i> 30(25): 6167-6174 (1991)	
	AX2	DAVIS, T.R. et al, "Intrinsic Glycosylation Potentials of Insect Cell Cultures and Insect Larvae", <i>In Vitro Cell. Dev. Biol.</i> 31:659-663 (1995)	
	AY2	DESNICK, R.J. "Enzyme replacement and beyond", <i>J Inherit Metab Dis.</i> 24(2):251-65 (2001)	
	AZ2	ENG, C.M. et al, "A phase 1/2 clinical trial of enzyme replacement in fabry disease: pharmacokinetic, substrate clearance, and safety studies", <i>Am. J. Hum. Genet.</i> , 68(3): 711-22 (2001)	
	AR3	HAHN, C.N. et al, "Correction of murine galactosialidosis by bone marrow-derived macrophages overexpressing human protective protein/cathepsin A under control of the colony-stimulating factor-1 receptor promoter", <i>PNAS</i> 95:14880-85 (1998)	

Examiner Signature

Charles L. Fonda

Date Considered

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				Application Number	09/966893
				Filing Date	September 28, 2001
				First Named Inventor	D'Azzo
				Art Unit	1646
				Examiner Name	To be assigned
Sheet	3	of	5	Attorney Docket Number	SJ-01-0020

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
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CJF	AS3	HOLLISTER, J.R. et al, "Engineering lepidopteran insect for sialoglycoprotein production by genetic transformation with mammalian β 1,4-galactosyltransferase and α 2,6-sialyltransferase genes", <i>Glycobiology</i> 11: 1-9 (2001)			
	AT3	HSU, T. et al, "Differential N-Glycan Patterns of Secreted and Intracellular IgG Produced in <i>Trichoplusia ni</i> cells", <i>Journal of Biological Chemistry</i> 272(14): 9062-9070 (1997)			
	AU3	IDA, H. et al, "Effects of enzyme replacement therapy in thirteen Japanese pediatric patients with Gaucher Disease", <i>Eur. J. Pediatr.</i> 160(1): 21-5 (2001)			
	AV3	IOANNOU, Y.A. et al, "Fabry disease: preclinical studies demonstrate the effectiveness of alpha-galactosidase a replacement in enzyme-deficient mice", <i>Am. J. Hum. Genet.</i> 68(1): 14-25 (2001)			
	AW3	JARVIS, D.L. et al, "Biochemical Analysis of the N-Glycosylation Pathway in Baculovirus-Infected Lepidopteran Insect Cells", <i>Virology</i> 212: 500-511 (1995)			
	AX3	JARVIS, D.L. et al, "Modifying the insect cell N-glycosylation pathway with immediate early baculovirus Expression vectors", <i>Nature Biotechnology</i> 14:1288-1292 (1996)			
	AY3	JARVIS, D.L. et al, "Engineering N-glycosylation pathways in the baculovirus-insect cell system", <i>Current Opinion In Biotechnology</i> 9: 528-533 (1998)			
	AZ3	JARVIS, D.L. et al, "Mutational Analysis of the N-Linked Glycans on <i>Autographa californica</i> Nucleopolyhedrovirus gp64", <i>Journal of Virology</i> 72(12): 9459-9469 (1998)			
	AR4	JARVIS, D.L. et al, "Novel baculovirus expression vectors that provide sialylation of recombinant glycoproteins in lepidopteran insect cells", <i>J. Virol.</i> 75(13): 6223-27 (2001)			
	AS4	KAKKIS, E.D. et al, "Enzyme-replacement therapy in mucopolysaccharidosis I", <i>N. Engl. J. Med.</i> 344(3): 182-188 (2001)			
	AT4	KAULI, R. et al, "Delayed Growth in Puberty in Patients with Gaucher Disease Type 1: Natural History And Effects of Splenectomy and/or Enzyme Replacement Therapy", <i>Isr. Med. Assoc. J.</i> 2(2): 158-63 (2000)			
	AU4	KAWAR, Z. et al, "Insect cells encode a class II α -Mannosidase with Unique properties", <i>J. Biol. Chem.</i> 276(19): 16335-40 (2001)			
	AV4	LEW, D.B. et al, "Mitogenic effect of lysosomal hydrolases on bovine tracheal myocytes in culture", <i>J. Clin. Invest.</i> , 99: 1969-1975 (1991)			
	AW4	LEW, D.B. et al, "A mannose receptor mediates mannose-rich glycoprotein-induced mitogenesis in bovine airway smooth muscle cells", <i>J. Clin. Invest.</i> 94:1855-1863 (1994)			
	AX4	LICARI, P.J. et al, "Insect Cell Hosts for Baculovirus Expression Vectors Contain Endogenous Exoglycosidase Activity", <i>Biotechnol. Prog.</i> 9:146-152 (1993)			
	AY4	LIN, L. et al, "Production and characterization of recombinant human CLN2 protein for enzyme-replacement therapy in late infantile neuronal ceroid lipofuscinosis", <i>Biochem J.</i> 357: 49-55 (2001)			
	AZ4	LIU, Z. et al, "TNF- α and IL-1 α induce mannose receptors and apoptosis in glomerular mesangial but not endothelial cells", <i>Am. J. Physiol.</i> 270: C1595-1601 (1996)			
	AR5	LUTZ, D.A. et al, "Natural, high-mannose glycoproteins inhibit ROS binding and ingestion by RPE cell cultures", <i>Exp. Eye Res.</i> 61: 487-493 (1995)			
	AS5	MAGNUSSON, S. et al, "Endocytosis of ricin by rat liver cells <i>in vivo</i> and <i>in vitro</i> is mainly mediated by mannose receptors on sinusoidal endothelial cells", <i>Biochem J.</i> 291: 749-755 (1993)			
	AT5	MARCHAL, I. et al, "Glycoproteins from insect cells: Sialylated or Not?", <i>Biol. Chem.</i> 382(2): 151-159 (2001)			

Examiner Signature	<i>Christie L. Mandel</i>	Date Considered	3/18/03
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CZJ	AU5	MARTIN, B.M. et al, "Glycosylation and processing of high levels of active human glucocerebrosidase in Invertebrate cells using a baculovirus expression vector", <i>DNA</i> 7(2): 99-106 (1988)	
	AV5	OGONAH, O.W. et al; "Isolation and Characterization of an Insect Cell Line Able to Perform Complex N-Linked Glycosylation on Recombinant Proteins" <i>Biotechnology</i> 14: 197-202 (1996)	
	AW5	PASTORES, G.M. et al, "Enzyme-replacement therapy for Anderson-Fabry disease", <i>Lancet</i> , 358(9282): 601-603 (Aug. 25 2001)	
	AX5	REIS eSOUSA, C. et al, "Phagocytosis of antigens by langerhans cells in vitro", <i>J. Exp. Med.</i> 178: 509-519 (1993)	
	AY5	ROULIEUX-BONNIN, F. et al, "Transcriptional expression of mannose receptor gene during differentiation of human macrophages", <i>Biochem. Biophys. Res. Comm.</i> 217: 106-112 (1995)	
	AZ5	RUDENKO, G. et al, "Three-dimensional structure of the human protective protein; structure of the precursor Form suggests a complex activation mechanism", <i>Structure</i> 3(11): 1249-1259 (1995)	
	AR6	RUDENKO, G. et al, "The atomic model of the human protective protein/cathepsin A suggests a Structural basis for galactosialidosis", <i>PNAS</i> 95: 621-625 (1998)	
	AS6	SALLUSTO, F. et al, "Dendritic cells use macropinocytosis and the mannose receptor to concentrate macromolecules in the major histocompatibility complex class II compartments: Downregulation by cytokines and bacterial products", <i>J. Exp. Med.</i> 182: 389-400 (1995)	
	AT6	SCHIFFMANN, R. et al, "Enzyme replacement therapy in Fabry Disease: a randomized controlled trial", <i>JAMA</i> , 285(21): 2743-2749 (2001)	
	AU6	SEO, N. et al, "Mammalian glycosyltransferase expression allows sialoglycoprotein production by baculovirus-infected insect cells", <i>Protein Expr. Purif.</i> 22(2):234-41 (2001)	
	AV6	SHEPARD, V.L. et al, "Isolation and characterization of a mannose receptor from human pigment epithelium" <i>Invest. Ophthalmol. Vis. Sci.</i> 32(6): 1779-1784 (1991)	
	AW6	SLY, W.S. et al, "Active site mutant transgene confers tolerance to human beta - glucuronidase without affecting the phenotype of MPS VII mice", <i>PNAS</i> 98(5): 2205-10 (Feb 27, 2001)	
	AX6	STAHL, P.D. et al, "The mannose receptor is a pattern recognition receptor involved in host defense", <i>Current Opinion in Immunology</i> 10: 50-55 (1998)	
	AY6	STEED, P.M. et al, "Characterization of recombinant human cathepsin B expressed at high levels in baculovirus", <i>Protein Science</i> 7(9): 2033-37 (1998)	
	AZ6	STEHLE, S.E. et al, "A Soluble Mannose Receptor Immunoadhesin Enhances Phagocytosis of <i>Pneumocystis Carinii</i> by Human Polymorphonuclear Leukocytes <i>In Vitro</i> ", <i>Scandinavian Journal of Immunology</i> 52: 131-137 (2000)	
	AR7	TAYLOR, M.E., "Structure and Function of the Macrophage Mannose Receptor", <i>Results and Problems in Cell Differentiation</i> 33:105-121 (2001)	

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